Remarks

Claims 1-41 are pending in this application. No claims have been allowed. The enclosed SIDS provides a copy of Vareckova et al., *Characterization of alkyd resins by size exclusion chromatography coupled with a multi-angle light scattering photometer*, Analytica Chimica Acta 557 (2006) 31-36. Vareckova et al. was available online beginning June 27, 2005 (*viz.*, 10 days after applicants' June 17, 2005 filing date) and is not prior art. Vareckova et al. is being provided to show polydispersity values for a series of alkyd resins and is discussed in more detail below.

Clarification is requested as to the status of claims 30 and 39. The Office Action recited seven formal rejections under 35 U.S.C. §103, but did not formally reject claim 30. Page 3 of the Office Action does however refer to claim 30 when discussing the rejection of claims 1-18, 21-25 and 27-29 under 35 U.S.C. §103(a) as being unpatentable over Swarup et al. Claim 39 was formally rejected on pages 7 and 8 of the Office Action, but page 5 of the Office Action also refers to claim 39 when discussing the rejection of claims 31-37 and 40 under 35 U.S.C. §103(a) as being unpatentable over Swarup et al.

Rejection of Claims 1-18, 21-25 and 27-29 under 35 U.S.C. §103(a)

Claims 1-18, 21-25 and 27-29 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,087,464 (Swarup et al.), on grounds *inter alia* that:

> *"Considering Claim 1: Swarup et al. teaches a coating composition (2:15-18) comprising an alkyd resin with a polydispersity of greater then 1/less than 2 (11:34-41) that is the reaction product of a polyester component (13:38-42) and a fatty acid component (13:53-65) that is preferably saturated (13:65-67); and a amino resin crosslinker (14:34-39). Swarup et al. also teaches the composition as having low discoloration/being substantially color stable (10:18-20).*
>
> *"Swarup et al. teaches a polydispersity greater than 1. This overlaps with the claimed range of less than about 2. In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a* prima facie *case of obviousness exists.* In re Wertheim, *541 F.2d 257, 191 USPQ 90 (CCPA 1976);* In re Woodruff, *91 9 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). See MPEP § 2144.05.*

> *"The Office realizes that all of the claimed effects or physical properties are not positively stated by the reference(s). However, the reference(s) teaches all of the claimed ingredients. Therefore, the claimed effects and physical properties, i.e. the color stability, would implicitly be achieved by a composition with all the claimed ingredients. If it is the applicant's position that this would not be the case: (1) evidence would need to be provided to support the applicant's position; and (2) it would be the Office's position that the application contains inadequate disclosure that there is no teaching as to how to obtain the claimed properties with only the claimed ingredients."* (see the Office Action at pages 2-3).

Applicants request reconsideration. Notwithstanding the statements in the Office Action, Swarup et al. nowhere "teaches" an alkyd resin with a polydispersity "greater [than] 1/less than 2", and no such teaching appears at the cited passage in col. 11, lines 34-41. Applicants (and Dow Chemical Co.) have already explained that in real life, polymer polydispersity is always greater than 1, see the February 27, 2004 Internet Archive web page at http://web.archive.org/web/20040227024642/http://www.dow.com/styron/tech/faqs/poly-general.htm#three). Swarup et al.'s statement that their polyol has a polydispersity greater than 1 is essentially meaningless. For a polymer this will always be the case. It is like saying that the polyol will have a molecular weight. Swarup et al. say absolutely nothing at all regarding a polydispersity "less than 2" – this statement in the Office Action has been made through improper reliance on applicants' disclosure, does not appear in the cited Swarup et al. passage at col. 11, lines 34-41, and has not been shown to be found anywhere else in Swarup et al. Swarup et al. nowhere say that the polydispersity should be **less than any value**, let alone less than about 2. Moreover, Swarup et al. nowhere attribute any property changes to alteration in the polydispersity value (contrast applicant's specification, e.g., at paragraph 0021).

The Office Action also relies on MPEP §2144.05. MPEP §2144.05 II. B is in fact germane to the present rejection ("A particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation.") Swarup et al. do not recognize polydispersity as a result-effective

variable. There is no basis whatever in Swarup et al. for varying the polydispersity of an alkyd resin, nor for optimizing polydispersity, nor for making a coating composition with an alkyd resin whose polydispersity is less than about 2.

Notwithstanding the statements in the Office Action, Swarup et al. nowhere "teaches" an alkyd resin composition "having low discoloration/being substantially color stable". The cited passage at col. 10, lines 18-20 concerns Swarup et al.'s phenolic esters made from the reaction of a hydroxybenzoic acid and an epoxy compound (see e.g., col. 8, line 45 through col. 10, line 32), not alkyd resins.

Regarding the Office Action's statements that "the claimed effects and physical properties, i.e. the color stability, would implicitly be achieved by a composition with all the claimed ingredients" and that "If it is the applicant's position that this would not be the case: (1) evidence would need to be provided to support the applicant's position", applicants are not able to submit any polydispersity evidence relating to Swarup et al.'s alkyd resins. Swarup et al. name a number of reactants which could be used to make alkyd resins, including seven dicarboxylic acids or acid anhydrides, ten oils, and eleven fatty acids (see e.g., col. 13, lines 45-67). Swarup et al. do not name any specific polyhydric alcohols (see e.g., col. 13, lines 43-45) and do not exemplify any specific alkyd resins. Swarup et al.'s list of reactants is thus incomplete insofar as the polyhydric alcohols are concerned, and involves thousands of potential permutations insofar as the dicarboxylic acids or acid anhydrides, oils, and fatty acids are concerned. Swarup et al.'s disclosure does not enable applicants (or anyone else for that matter) to replicate any particular alkyd resin from Swarup et al. and measure its polydispersity.

In lieu of experimental results based on Swarup et al., the Examiner is requested to review the accompanying copy of Vareckova et al. Vareckova et al. is as noted above not prior art. Vareckova et al. say however that "Alkyd resins are highly polydispersed polymers and therefore their molecules elute over a broad range of elution volumes." (see page 34). Vareckova et al. also say that alkyd resins are typically characterized by conventional SEC (size exclusion chromatography) with column calibration based on polystyrene (PS) standards (see page 31). Vareckova et al.'s Table 1 (see page 33) shows Mn and Mw values for a series of alkyd resins made from soybean oil, pentaerythritol or glycerol or their 1:1 mixture, and

phthalic anhydride (see page 32). Table 1 does not recite polydispersity values but does include Mn and Mw values obtained via SEC, as well as Mn and Mw values obtained using an alternative measurement technique proposed by Vareckova et al., namely SEC using a multi-angle light scattering photometer (SEC-MALS). For the Examiner's convenience Vareckova et al.'s Table 1 SEC data has been reproduced below along with calculated polydispersity values based on Vareckova et al.'s SEC measurements:

Vareckova et al. Table 1

(Revised to show Polydispersity Values based on SEC)

Mn (SEC)	Mw (SEC)	Polydispersity (Ratio Mw/Mn)
2820	12170	4.3
3168	24405	7.7
3600	60342	16.8
3801	86629	22.8
3851	115188	29.9
3965	148718	37.5
3774	346767	91.9

Vareckova et al.'s alkyd resin series exhibited polydispersity values from 4.3 to 91.9. This data reinforces Vareckova et al.'s statement that alkyd resins normally are highly polydispersed polymers. If asked to consider the matter, a person having ordinary skill in the art would expect that alkyd resins would have polydispersities well above 2, and would regard coating compositions containing "an alkyd resin having a polydispersity of less than about 2" as unexpected and not obvious from Swarup et al.

Regarding the Office Action's statements that "it would be the Office's position that the application contains inadequate disclosure that there is no teaching as to how to obtain the claimed properties with only the claimed ingredients", applicants respectfully disagree.

If asked to do so, persons skilled in the art understand how to vary or limit polydispersity. For example, polydispersity may be reduced by avoiding excessive amounts of trifunctional or higher-functional reactants so as to control the extent of branching, and by adding the reactants using a suitable addition order and addition rate so as to obtain more uniform rather than less uniform polymer segment lengths.

Regarding the additional assertions in the Office Action at pages 3-4 concerning claims 2-18, 21-25, 27-29 (and if also intended to be included in the rejection, claim 30), applicants rely in the interest of brevity on the arguments given above for claim 1 and on the arguments at pages 10-13 of applicants' July 14, 2008 Amendment. Swarup et al. fail to provide any teaching, suggestion or motivation to vary polydispersity, let alone to make a coating composition with an alkyd resin having a polydispersity less than about 2. Applicants accordingly request reconsideration and withdrawal of the 35 U.S.C. §103(a) rejection of claims 1-18, 21-25 and 27-29 as being unpatentable over Swarup et al.

Rejection of claims 31-37 and 40 under 35 U.S.C. §103(a)

Claims 31-37 and 40 were rejected under 35 U.S.C. §103(a) as being unpatentable over Swarup et al., on grounds that:

> *"Considering Claims 31-33: Swarup et al. teaches a coating composition (2:15-18) comprising an alkyd resin with a polydispersity of greater then 1/less than 2 (11:34-41) that is the reaction product of a polyester component (13:38-42) and a fatty acid component (13:53-65) that is preferably saturated (13:65-67). Swarup et al. teaches the polyester being a reaction product of a aliphatic polyol and a acid that is preferably phthalic anhydride, isophthlaic acid, succinic acid, or adipic acid (13:43-52) and the alkyd resin having a number average molecular weight of from 500 to 20,000 (13:35-42).*
>
> *"Swarup et al. teaches a polydispersity greater than 1. This overlaps with the claimed range of less than about 2. In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists.* In re Wertheim, *541 F.2d 257, 191 USPQ 90 (CCPA 1976);* In re Woodruff, *919 F.2d*

1575, 16 USPQ2d 1934 (Fed. Cir. 1990). See MPEP § 2144.05." (see the Office Action at pages 4-5).

Reconsideration is requested. As discussed above, Swarup et al. nowhere say that the polydispersity should be less than any value, let alone less than about 2. Swarup et al. do not say what the polydispersity of their alkyd resins actually might be and do not provide the weight average molecular weight values which would be needed to calculate polydispersity values. Moreover, Swarup et al. nowhere attribute any property changes to alteration in the polydispersity value (contrast applicant's specification, e.g., at paragraph 0021). See also the above-quoted extract from MPEP §2144.05 II. B, and the enclosed copy of *Ex Parte Whelan*, 89 USPQ2d 1078 (BPAI, 2008). The deficiencies of the present rejection resemble those discussed in *Ex parte Whelan*, where the cited references similarly failed to provide any teaching, suggestion or motivation to vary a factor (in *Whelan*, viscosity) to levels recited in the rejected claims. In the interest of brevity applicants also rely on their arguments given above concerning claim 1-18, 21-25 and 27-29 and on the arguments at page 14 of applicants' July 14, 2008 Amendment. Applicants accordingly request reconsideration and withdrawal of the 35 U.S.C. §103(a) rejection of claims 31-37 and 40 (and if also intended to be included in the rejection, claim 39) as being unpatentable over Swarup et al.

Rejection of claim 41 under 35 U.S.C. §103(a)

Claim 41 was rejected under 35 U.S.C. §103(a) as being unpatentable over Swarup et al., on grounds that:

"Considering Claim 41: Swarup et al. teaches a steel panel/metal substrate coated with a a coating composition (2:15-18) comprising an alkyd resin with a polydispersity of greater then 1/less than 2 (11:34-41) that is the reaction product of a polyester component (13:38-42) and a fatty acid component (13:53-65) that is preferably saturated (13:65-67); and a amino resin crosslinker (14:34-39). Swarup et al. also teaches the composition as having low discoloration/being substantially color stable (10:18-20). Swarup et al. also teaches the alkyd resin as having a number average molecular weight of from 500 to 20,000 (13:35-42).

"Swarup et al. teaches a polydispersity greater than 1. This overlaps with the

claimed range of less than about 2. In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. In re Wertheim, *541 F.2d 257, 191 USPQ 90 (CCPA 1976);* In re Woodruff, *919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). See MPEP § 2144.05."* (see the Office Action at pages 5-6).

Reconsideration is requested. As discussed above, Swarup et al. do not teach an alkyd resin composition "having low discoloration/being substantially color stable", and the cited passage at col. 10, lines 18-20 concerns phenolic esters, not alkyd resins. Swarup et al. also do not discuss rebaking or color stability and do not provide experimental results showing a composition that is "substantially color stable" as recited in Applicants' claim 41. In the interest of brevity applicants also rely on their arguments given above concerning claim 1 and on the arguments at page 15 of applicants' July 14, 2008 Amendment. Applicants accordingly request withdrawal of the 35 U.S.C. §103(a) rejection of claim 41 as being unpatentable over Swarup et al.

Rejection of claims 19 and 20 under 35 U.S.C. §103(a)

Claims 19 and 20 were rejected under 35 U.S.C. §103(a) as being unpatentable over Swarup et al. as applied to claim 1 above, and further in view of U.S. Patent No. 5,269,839 (Sodhi), on grounds that:

"Considering Claims 19 and 20: Swarup et al. teaches the composition of claim 1 as shown above.

"Swarup et al. does not teach the acid number as being as claimed. However, Sodhi teaches an alkyd resin for coatings that has an acid number of between 5 and 10 (2:29-43). Swarup et al. and Sodhi are combinable as they are concerned with the same field of endeavor, namely alkyd resin coatings. It would have been obvious to a person having ordinary skill in the art at the time of invention to have used an alkyd resin with the acid number of Sodhi in the coating of Swarup et al., and the motivation to do so would have been, as Sodhi suggests to provide a clear resin (1:23)." (see the Office Action at page 6).

The Office Action also asserts that:

"B) In response to applicant's argument that there is no suggestion to combine the Swarup et al. and Sodhi references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See In re Fine, *837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and* In re Jones, *958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, it would have been obvious to a person having ordinary skill in the art at the time of invention to have used an alkyd resin with the acid number of Sodhi in the coating of Swarup et al., and the motivation to do so would have been, as Sodhi suggests, the low acid value shows that the reaction between the polyester and the fatty acid has gone to completions (2:29-43)."* (see the Office Action at page 8).

Reconsideration is requested. For the reasons already discussed above, the Office Action is incorrect when it asserts that "Swarup et al. teaches the composition of claim 1". Swarup et al. do not do so, for at least the reason that Swarup et al. do not show a coating composition made using "an alkyd resin having a polydispersity of less than about 2".

Sohdi says nothing regarding molecular weight or polydispersity, and provides no basis for selecting a coating composition with "an alkyd resin having a polydispersity of less than about 2".

Thus even if Swarup et al. and Sohdi were to be combined as proposed in the Office Action, the result still would not provide a coating composition containing "an alkyd resin having a polydispersity of less than about 2" as recited in rejected claims 19 and 20.

Applicants accordingly request withdrawal of the 35 U.S.C. §103(a) rejection of claims 19 and 20 as being unpatentable over Swarup et al. in view of Sodhi.

Rejection of claim 26 under 35 U.S.C. §103(a)

Claim 26 was rejected under 35 U.S.C. §103(a) as being unpatentable over Swarup et al. as applied to claim 1 above, and further in view of U.S. Patent Application Publication No. 2002/0147270 A1 (Kuo et al.) on grounds that:

"Considering Claim 26: Swarup et al. teaches the composition of claim 1 as shown above. Swarup et al. also teaches adding a flow control agent to the composition (17:59).

"Swarup et al. does not teach the composition as comprising a wax. However, Kuo et al. teaches adding a polyolefin/polyethylene wax (¶0070) to an alkyd resin coating (abstract). Swarup et al. and Hall are analogous art as they are concerned with the same field of endeavor, namely alkyd resin coatings. It would have been obvious to a person having ordinary skill in the art at the time of invention to have added the wax of Kuo et al. to the coating of Swarup et al., and the motivation to do so would have been, as Kuo et al. suggests, polyolefin waxes are well known flow control agents (¶0070)." (see the Office Action at pages 6-7).

Reconsideration is requested. For the reasons already discussed above, the Office Action is incorrect when it asserts that "Swarup et al. teaches the composition of claim 1". Swarup et al. do not show a coating composition made using "an alkyd resin having a polydispersity of less than about 2".

Applicants agree that Swarup et al. do not teach their composition as comprising a wax. However, no proper basis has been provided for selecting only a portion of Kuo et al. (its four word mention in the last two lines of paragraph 0070 of "polyamide wax, polyolefin wax" as possible "viscosity, suspension and flow control agents") while ignoring the other parts of Kuo et al. which teach away from applicants' claimed coating compositions. Kuo et al. form modified alkyd polymers by incorporating "polyol and/or diol-containing latex compositions" in an alkyd polymerization reaction (see e.g., paragraphs 0007 and 0017). Kuo et al. do not mention polydispersity and do not discuss the effect of polydispersity on coating properties. Kuo et al. do however provide Mn and Mw values for their latex polymers (see e.g., paragraphs 0039, 0076, 0080, 0091, 0097, 0108 and 0116). The polydispersities of Kuo et al.'s latex polymers may be calculated from these values, and range from about 4.6 (Example 12, see paragraph 108) to about 13.4 (Example 1, see paragraph 0076). Further reaction of these latex polymers to form modified alkyd resins would further increase the polydispersity values, and would not provide a coating composition comprising an alkyd resin

"having a polydispersity of less than about 2" as recited in rejected claim 26. Thus even if Swarup et al. and Kuo et al. were to be combined, there is no basis in Swarup et al., Kuo et al. or any combination of Swarup et al. and Kuo et al. for selecting a coating composition with "an alkyd resin having a polydispersity of less than about 2". Applicants accordingly request withdrawal of the 35 U.S.C. §103(a) rejection of claim 26 as being unpatentable over Swarup et al. as applied to claim 1 above, and further in view of Kuo et al.

Rejection of claim 38 under 35 U.S.C. §103(a)

Claim 38 was rejected under 35 U.S.C. §103(a) as being unpatentable over Swarup et al. as applied to claim 31 above, and further in view of Sodhi, on grounds that:

"Considering Claim 38: Swarup et al. teaches the composition of claim 31 as shown above.

"Swarup et al. does not teach the acid number as being as claimed. However, Sodhi teaches an alkyd resin for coatings that has an acid number of between 5 and 10 (2:29-43). Swarup et al. and Sodhi are analogous art as they are concerned with the same field of endeavor, namely alkyd resin coatings. It would have been obvious to a person having ordinary skill in the art at the time of invention to have used an alkyd resin with the acid number of Sodhi in the coating of Swarup et al., and the motivation to do so would have been, as Sodhi suggests, the low acid value shows that the reaction between the polyester and the fatty acid has gone to completions (2:29-43)" (see the Office Action at page 7).

Reconsideration is requested. In the interest of brevity, applicants rely on their arguments given above concerning the rejection of claim 1 over Swarup et al. and the rejection of claims 19 and 20 over Swarup et al. in view of Sohdi. Neither Swarup et al. nor Sohdi shows a coating composition made using "an alkyd resin having a polydispersity of less than about 2", not would their combination. Thus even if Swarup et al. and Sohdi were to be combined as proposed in the Office Action, the result still would not provide an alkyd resin composition "wherein the alkyd resin has ... a polydispersity of less than about 2" as recited in rejected claim 38. Applicants accordingly request withdrawal of the 35 U.S.C. §103(a) rejection of claim 38 as being unpatentable over Swarup et al. as applied to claim 31 above, and further in

view of Sodhi.

Rejection of claim 39 under 35 U.S.C. §103(a)

Claim 39 was rejected under 35 U.S.C. 103(a) as being unpatentable over Swarup et al. as applied to claim 31 above, on grounds that:

"Considering Claim 39: Swarup et al. teaches the composition of claim 31 as shown above. Swarup et al. also teaches composition as having a low viscosity (6:13-36).

"Swarup et al. does not teach the alkyd resin having the claimed viscosity. However, it is well known in the art to optimize result effective variables such as viscosity. It would have been obvious to a person having ordinary skill in the art at the time of invention to have used a resin with the claimed viscosity, and the motivation to do so would have been, as Swarup et al. suggests, to provide a high solids content coating with low VOC (6:27-36)." (see the Office Action at pages 7-8).

Reconsideration is requested. In the interest of brevity, applicants rely on their arguments given above concerning the rejections of claims 1 and 31 over Swarup et al. Swarup et al. do not show a coating composition made using "an alkyd resin having a polydispersity of less than about 2". The cited passage at col. 6 of Swarup et al. refers to the viscosity of a blend of "phenolic ester alcohol, polyol and isocyanate compound", not to the viscosity of an alkyd resin as is recited in claim 39. Even if the viscosity of Swarup et al.'s compositions were to be optimized as proposed in the Office Action, the result would at best involve varying the molecular weight of Swarup et al.'s polymeric vehicle (see e.g., col. 12, lines 41-59), not varying the polydispersity of an alkyd resin, let alone using an alkyd resin having a polydispersity of less than about 2. Applicants accordingly request withdrawal of the 35 U.S.C. §103(a) rejection of claim 39 as being unpatentable over Swarup et al. as applied to claim 31 above.

Conclusion

Applicants have made an earnest effort to address the objections and rejections. Withdrawal of each of them and passage of the application to the issue branch are accordingly

requested. The Examiner is encouraged to telephone the undersigned attorney if there are any questions regarding this application or this response.

Respectfully submitted on behalf
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte THOMAS J. WHALEN II, CHINH N. TRAN, NOAH M. ROTH, and RICHARD J. GREFF

Appeal 2007-4423
Application 10/281,142
Technology Center 1600

Decided: July 23, 2008

Before MICHAEL R. FLEMING, *Chief Administrative Patent Judge*, and SALLY G. LANE, ERIC GRIMES, RICHARD M. LEBOVITZ, and FRANCISCO C. PRATS, *Administrative Patent Judges*.

GRIMES, *Administrative Patent Judge.*

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a composition for embolizing an aneurysm, which the Examiner has rejected for anticipation, obviousness, and obviousness-type double patenting. We have jurisdiction under 35 U.S.C. § 6(b). We reverse.

STATEMENT OF THE CASE

The Specification states that "[e]mbolizing compositions (embolic compositions) heretofore disclosed in the art include those comprising a biocompatible polymer, a biocompatible solvent and a contrast agent which allowed visualization of the *in vivo* delivery of the composition" (Spec. 3). "Such compositions typically contain no more than about 8 weight percent of biocompatible polymer based on the weight of the total composition" (*id.*).

The Specification states that prior art embolic compositions had the drawback that "upon ejection of the embolic composition in a vascular site, the coherent mass subsequently formed was often distal and not proximate the ejection port of the catheter. Moreover, upon solidification, the solid mass formed was often linear in shape (i.e., having a 'string shape')." (*Id.*) This property of the prior art compositions is said to lead to difficulty in site-specific delivery of the embolic composition, and the danger that fragments of the solidified composition will embolize an artery or "lodg[e] at undesired locations in the vasculature" (*id.*).

The Specification discloses that "formation of a solid non-migratory mass having a substantially contiguous or 'ball' shape can be achieved by use of embolic compositions . . . [having] a viscosity of at least 150 cSt at 40° C" (*id.*).[1] According to the Specification, "the viscosity of these compositions is significantly higher than those containing 8 weight percent polymer, thereby rendering it difficult to employ conventional delivery

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[1] Viscosity can be measured in units of centiStokes (cSt) or centipoise (App. Br. 6).

means (e.g., syringe). . . . However, delivery means such as the threaded syringes described [in two provisional patent applications] now renders the use of these highly viscous compositions practical." (*Id.* at 4.)

Claims 1-17 are pending and on appeal. Claim 1 is representative and reads as follows:

1. A composition capable of embolizing an aneurysm at a vascular site comprising:

(a) a biocompatible polymer;

(b) a biocompatible contrast agent wherein a sufficient amount of said contrast agent is employed in said composition to effect visualization *in vivo*; and

(c) a biocompatible solvent which solubilizes said biocompatible polymer

wherein a sufficient amount of said polymer are [sic] employed in said composition such that, upon delivery to a vascular site, a polymer precipitate forms which embolizes said vascular site; and

further wherein the biocompatible polymer has a molecular weight sufficient to impart to the composition a viscosity of at least about 150 cSt at 40° C.

The components recited in claim 1 – biocompatible polymer, biocompatible contrast agent, and biocompatible solvent – are the same as those in known embolic compositions (Spec. 3). Thus, if claim 1 differs from the prior art, it is by virtue of the limitation that "the biocompatible polymer has a molecular weight sufficient to impart to the composition a viscosity of at least about 150 cSt at 40° C." Claim 2, the only other independent claim on appeal, also includes this limitation.

As we interpret it, this limitation requires only that the claimed composition have "a viscosity of at least about 150 cSt at 40° C." Although the claim also refers to the molecular weight of the polymer in the

composition, that reference does not limit the claim: If a composition comprises the recited polymer and has the recited viscosity, then the polymer necessarily "has a molecular weight sufficient to impart" the resulting viscosity, at whatever concentration of polymer is present.

The Examiner has rejected the claims as follows:

- Claims 1-17 stand rejected for obviousness-type double patenting based on claims 1-5 of Greff '568,[2] claims 1-46 of Evans,[3] claims 1-6 of Greff '508,[4] and claims 1-6 of Greff '767;[5]
- Claims 1-13 and 15-17 stand rejected under 35 U.S.C. § 103 as obvious in view of Evans;
- Claims 1-17 stand rejected under 35 U.S.C. § 103 as obvious in view of Greff '767; and
- Claims 1-6, 9, 10, and 14-17 stand rejected under 35 U.S.C. §§ 102(b) or 103 as anticipated by or obvious in view of Taki.[6]

DOUBLE PATENTING

The Double Patenting Issue

Claims 1-17 stand rejected for obviousness-type double patenting based on claims 1-5 of Greff '568, claims 1-46 of Evans, claims 1-6 of Greff '508, and claims 1-6 of Greff '767.[7] The Examiner's position is:

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[2] Greff et al., U.S. Patent 5,580,568, issued Dec. 3, 1996.
[3] Evans et al., U.S. Patent 5,695,480, issued Dec. 9, 1997.
[4] Greff et al., U.S. Patent 5,581,508, issued Dec. 22, 1998.
[5] Greff et al., U.S. Patent 5,667,767, issued Sept. 16, 1997.
[6] Taki et al., "A new liquid material for embolization of arteriovenous malformations," 11 *AJNR, Amer. Journal of Neuroradiology* 163 (1990).
[7] In the Answer, the Examiner also rejected claims 1-17 based on claims 1-15 of U.S. Patent 6,531,111 (Ans. 4). However, Appellants have filed a

> both the patented claims and the instant pending claims are directed to compositions comprising a biocompatible polymer, a biocompatible contrast agent and a biocompatible solvent. Therefore, each set of the patented claim[s] anticipates the scope of the pending claim[s]. Accordingly, it would have been obvious to one of ordinary skill in the art at the time of invention to practice the pending claims when in possession of the patented claims. Thus, the pending claims are obvious variants of the patented claims.

(Ans. 4.)

Appellants contend that "[t]here is no teaching of viscosity in any of Claim 1-5 of the '568 patent" (App. Br. 11); "[t]here is no teaching, in either the specification or the claims of [Evans], of viscosities of 150 centiStokes at 40°C" (*id.* at 12); "it is unclear why Claims 1-17 [sic] of [Greff '508] would motivate one skilled in the art to make and use the high viscosity embolic composition of the claims on Appeal" (*id.* at 13); and "for the same reasons noted for the '508 patent, the rejection of Claims 1-17 . . . over Claims 1-6 of the '767 patent is in error" (*id.*).

In view of these conflicting positions, the double-patenting issue presented is: Are the rejected claims directed to a composition that is an obvious variant of the compositions claimed in Greff '568, Evans, Greff '508, or Greff '767?

Findings of Fact Relating to Double Patenting

FF1. Claim 1 of Greff '568 is directed to a composition comprising:

(a) from about 2.5 to about 8 weight percent of a cellulose diacetate having an acetyl content of from about 31 to about 40 weight percent;

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terminal disclaimer with respect to the '111 patent (terminal disclaimer received July 19, 2004) so that basis of the rejection has been overcome.

(b) from about 10 to about 40 weight percent of a water insoluble contrast agent selected from the group consisting of tantalum, tantalum oxide and barium sulfate;

(c) from about 52 to about 87.5 weight percent of a biocompatible solvent

wherein the weight percent of the cellulose diacetate, water insoluble contrast agent and biocompatible solvent is based on the total weight of the complete composition.

(Greff '568, col. 9, ll. 37-50.)

FF2. Claim 1 of Evans is directed to a composition comprising:

(a) from about 2.5 to about 8.0 weight percent of a biocompatible polymer;

(b) from about 10 to about 40 weight percent of a water insoluble, biocompatible contrast agent having an average particle size of about 10 μm or less; and

(c) from about 52 to about 87.5 weight percent of a biocompatible solvent

wherein the weight percent of the polymer, contrast agent and biocompatible solvent is based on the total weight of the complete composition.

(Evans, col. 11, ll. 47-58.)

FF3. Claim 1 of Greff '508 is directed to a composition comprising:

(a) from about 2.5 to about 8.0 weight percent of an ethylene vinyl alcohol copolymer;

(b) from about 20 to about 40 weight percent of a water insoluble contrast agent selected from the group consisting of tantalum, tantalum oxide and barium sulfate;

(c) from about 52 to about 87.5 weight percent of a biocompatible solvent

wherein the weight percent of each of the components is based on the total weight of the complete composition.

(Greff '508, col. 10, ll. 7-16.)

FF4. Claim 1 of Greff '767 is directed to a composition comprising:

(a) from about 2.5 to about 8.0 weight percent of an ethylene vinyl alcohol copolymer;

(b) from about 10 to about 40 weight percent of a water insoluble contrast agent selected from the group consisting of tantalum, tantalum oxide and barium sulfate;

(c) from about 52 to about 87.5 weight percent of a biocompatible solvent

wherein the weight percent of each of the components is based on the total weight of the complete composition.

(Greff '767, col. 9, ll. 37-50.)

FF5. Claims 1-5 of Greff '568, claims 1-46 of Evans, claims 1-6 of Greff '508, and claims 1-6 of Greff '767 do not limit the claimed compositions to those having a particular viscosity, and therefore encompass compositions having the components recited in those claims, in the recited concentrations, regardless of the viscosity of the resulting compositions.

FF6. The Examiner has not pointed to any evidence showing that any composition encompassed by claims 1-5 of Greff '568, claims 1-46 of Evans, claims 1-6 of Greff '508, or claims 1-6 of Greff '767 would inherently have a viscosity of at least about 150 cSt at 40° C.

Discussion of the Double Patenting Issue

We conclude that the Examiner has not shown that the composition of the claims on appeal is an obvious variant of the compositions of claims 1-5 of Greff '568, claims 1-46 of Evans, claims 1-6 of Greff '508, or claims 1-6 of Greff '767.

The analyses for obviousness under 35 U.S.C. § 103 and obviousness-type double patenting are not identical; for one thing, "[t]he objects of comparison are very different: Obviousness compares claimed subject matter to the prior art; nonstatutory double patenting compares claims in an

earlier patent to claims in a later patent or application." *Geneva Pharms., Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373, 1378 n.1 (Fed. Cir. 2003). The purpose of an obviousness-type double patenting rejection is "to prevent an unjustified extension of the term of the right to exclude granted by a patent by allowing a second patent claiming an obvious variant of the same invention to issue to the same owner later." *In re Berg*, 140 F.3d 1428, 1431 (Fed. Cir. 1998).

Here, all of the claims cited by the Examiner are limited to compositions containing less than about 8 weight percent polymer (FF1 to FF4). The instant Specification states that known embolic compositions typically contained less than about 8 weight percent polymer (Spec. 3) and that such compositions often formed undesirable "string shaped" masses (*id.*).

The Examiner has not directed us to evidence sufficient to show that any composition encompassed by the relied-upon patented claims – with less than about 8 weight percent polymer – would have a viscosity of 150 cSt at 40° C. Therefore, the Examiner's finding that the relied-upon patented claims anticipate the claims on appeal is not supported by the evidence.

The Examiner has not provided any other reasoned, fact-based explanation supported by the evidence of record to justify a conclusion that the compositions defined by the claims on appeal are obvious variants of the compositions of claims 1-5 of Greff '568, claims 1-46 of Evans, claims 1-6 of Greff '508, or claims 1-6 of Greff '767. We therefore reverse the rejections for obviousness-type double patenting.

REJECTIONS BASED ON THE PRIOR ART

The Obviousness and 102(b)/103 Issues

The Examiner finds that the compositions taught by Evans and Taki "inherently possess the same viscosity" as the claimed composition because they "comprise similar components[s] used in overlapping ranges of concentrations as those claimed" (Ans. 5-6; see also *id.* at 7). Alternatively, the Examiner concludes that the claimed compositions would have been obvious in view of the compositions taught by Evans, Greff '767, and Taki because "it would have been prima facie obvious to optimize the viscosity range of [the known] compositions by routine experimentation" (*id.* at 6, 7).

Appellants argue that Evans, Greff '767, and Taki refer to viscosity only in passing and when they do, they indicate that the disclosed compositions should have a viscosity well under 150 cSt (Evans and Greff '767) or are of "low viscosity" (Taki) and it is "unclear why [the prior art disclosures] would motivate one skilled in the art to make and use [a] high viscosity embolic composition" (App. Br. 12, 13-14, 15-16).

In view of these conflicting positions, the issue presented with respect to patentability over the cited prior art is: Do the disclosures of Evans, Greff '767, or Taki anticipate, or would they have rendered obvious, the claimed compositions to those of ordinary skill in the art?

Findings of Fact Relating to the Prior Art Rejections

FF7. The Examiner finds that "Evans' compositions have a viscosity of less than 60 centipoise at 20° C (see col 5, lines 37-43). Accordingly, Evans anticipates the limitations of the instant claims." (Ans. 5.)

FF8. The Examiner finds that "[a]lthough Evans does not specifically recite the instantly claimed viscosity of 150 cSt at 40° C . . . , Examiner takes the position that compositions disclosed by Evans inherently possess the same viscosity . . . as the instantly claimed invention, because Evans' compositions comprise similar component[s] used in overlapping ranges of concentrations" (Ans. 5-6).

FF9. The Examiner finds that a person of ordinary skill in the art "would have been motivated to optimize the viscosity of the Evans' final formulation, because he would have had a reasonable expectation of success in achieving the safest clinical outcome and avoiding transvenous passage" of the embolizing composition (Ans. 6).

FF10. The Examiner relies on the same reasoning in the rejections based on Greff '767 and Taki (Ans. 6-8).

FF11. Evans teaches compositions comprising a biocompatible polymer (2.5-8 wt %), a biocompatible contrast agent (10-40 wt %), and a biocompatible solvent (52-87.5 wt %) (Evans, col. 3, ll. 32-43).

FF12. Evans teaches that one preferred composition "has a viscosity equal to or less than 60 centipoise at 20° C" (Evans, col. 5, ll. 39-43).

FF13. According to Appellants, units of poise (or centipoise) are related to units of Stokes (or centiStokes) according to the equation Poise = Stokes x density (App. Br. 6).

FF14. The Examiner has not disputed that Poise = Stokes x density.

FF15. According to Appellants, "[f]or Newtonian fluids, it is well understood that viscosity decreases as temperature increases" (App. Br. 7).

FF16. The Examiner has not disputed that viscosity decreases as temperature increases.

FF17. Evans discloses that "all other factors being equal, copolymers having a lower molecular weight will impart a lower viscosity to the composition as compared to higher molecular weight copolymers. Accordingly, adjustment of the viscosity of the composition as necessary for catheter delivery can be readily achieved by mere adjustment of the molecular weight of the copolymer composition." (Evans, col. 5, ll. 44-50.)

FF18. Greff '767 teaches compositions comprising an ethylene vinyl alcohol copolymer (2.5-8 wt %), a contrast agent that is tantalum, tantalum oxide or barium sulfate (10-40 wt %), and a biocompatible solvent (52-87.5 wt %) (Greff '767, col. 3, ll. 37-48).

FF19. Greff '767 teaches that a composition comprising 6.8 weight percent of ethylene vinyl alcohol copolymer ("EVOH") in dimethyl sulfoxide ("DMSO") has a viscosity of approximately 60 centipoise at 20° C (Greff '767, col. 9, ll. 28-31).

FF20. Greff '767 teaches that addition of 38.5 weight percent metrizamide (a contrast agent; Greff '767, col. 9, ll. 4-6) to the composition of FF19 increased its viscosity to approximately 145 centipoise at 20° C (*id.* at col. 9, ll. 31-34).

FF21. Greff '767 teaches that addition of 35 weight percent tantalum or barium sulfate to a composition similar to that of FF19 did not materially alter its viscosity (Greff '767, col. 9, ll. 35-37).

FF22. Greff '767 states that the purpose of the compositions referred to in FF19 to FF21 was to "illustrate that certain embolizing agent/contrast

agent combinations provide for physical properties which make injection of the combination into vascular sites significantly more difficult" (Greff '767, col. 9, ll. 24-27).

FF23. Taki teaches an embolizing composition containing "5 g of solid ethylene vinyl alcohol copolymer (EVAL) and 35 g of powder metrizamide dissolved in 60 g of dimethyl sulfoxide (DMSO) as a solvent" (Taki 163).

FF24. Taki teaches that the "EVAL and DMSO mixture was of low viscosity and could be easily injected through the narrow lumen of the microballoon catheter, which was 150 cm in length" (Taki 168).

Discussion of the Obviousness and 102(b)/103 Issues

We determine that the Examiner has not made out a prima facie case that the claimed compositions are anticipated by Taki or would have been obvious in view of any of Evans, Greff '767, or Taki.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros., Inc. v. Union Oil Co.*, 814 F.2d 628, 631 (Fed. Cir. 1987). None of the references relied on by the Examiner expressly describes an embolizing composition having a viscosity of at least 150 cSt at 40° C as required by claim 1.

The Examiner has not provided an adequate basis – based on evidence or scientific reasoning – to support the finding that the "compositions disclosed by Evans inherently possess the same viscosity . . . as the instantly claimed invention" (FF8, Ans. 5-6). The Examiner reasons that "Evans' compositions comprise similar component[s] used in overlapping ranges of

concentrations," but even if some of the compositions encompassed by Evans' broad disclosure might have a viscosity of 150 cSt at 40° C, that possibility is not adequate to support a finding of inherent anticipation.

"Inherency . . . may not be established by probabilities or possibilities. The mere fact that a certain thing *may* result from a given set of circumstances is not sufficient." *In re Oelrich*, 666 F.2d 578, 581 (CCPA 1981). *See also Ex parte Skinner*, 2 USPQ2d 1788, 1789 (BPAI 1986) ("[T]he examiner must provide some evidence or scientific reasoning to establish the reasonableness of the examiner's belief that the functional limitation is an inherent characteristic of the prior art" before the burden is shifted to the applicant to disprove the inherency.).

The Examiner has not provided evidence or scientific reasoning to show that any specific composition disclosed by Evans is within the scope of the instant claims, and therefore has not made out a case of inherent anticipation by Evans. The Examiner's finding that "Evans anticipates the limitations of the instant claims" (FF7, Ans. 5) is not supported by the evidence of record. The Examiner also has not shown that Taki discloses a composition that expressly or inherently meets all the limitations of the instant claims. We therefore reverse the rejection for anticipation based on Taki.

The Examiner's obviousness rejections are based on the reasoning that a person of ordinary skill in the art "would have been motivated to optimize the viscosity of the Evans' [and Greff '767's and Taki's] final formulation[s], because he would have had a reasonable expectation of

success in achieving the safest clinical outcome and avoiding transvenous passage" of the embolizing composition (FF9, FF10; Ans. 6-8).

The Examiner has not made out a prima facie case that the claimed compositions would have been obvious based on the teachings of Evans, Greff '767, or Taki. While "the discovery of an optimum value of a variable in a known process is normally obvious," *In re Antonie*, 559 F.2d 618, 620 (CCPA 1977), this is not always the case. One exception to the rule is where the parameter optimized was not recognized in the prior art as one that would affect the results. *Id.*

Here, the Examiner has not pointed to any teaching in the cited references, or provided any explanation based on scientific reasoning, that would support the conclusion that those skilled in the art would have considered it obvious to "optimize" the prior art compositions by increasing their viscosity to the level recited in the claims. No reason to have done so is apparent to us based on the record. On the contrary, the references all suggest that low viscosity was a desired property in embolic compositions. Evans teaches that a preferred composition has a viscosity of 60 centipoise or less at 20° C (FF12). Appellants calculate, and the Examiner does not dispute, that 60 centipoise at 20° C corresponds to less than 75 cSt at 40° C (App. Br. 12). Therefore, Evans' preferred composition has a viscosity less than half of that required by the instant claims.

Likewise, Greff '767 teaches that a composition with a viscosity of 145 cSt at 20° C had "physical properties which make[ ] injection . . . into vascular sites significantly more difficult" (FF20, FF22) – and the only physical property of the composition discussed is its viscosity. In agreement

with the other references, Taki teaches that its composition had a low viscosity (FF24) and had the desirable property of being easily injected through a microballoon catheter (FF24).

Thus, the references teach that low viscosity is a desirable characteristic for embolic compositions. In our view, none of the cited references would have led a person of ordinary skill in the art to modify the known embolic compositions by increasing their viscosity to at least 150 cSt at 40° C. The Examiner has not adequately explained why such a modification would have been obvious.

The U.S. Supreme Court recently held that rigid and mandatory application of the "teaching-suggestion-motivation," or TSM, test is incompatible with its precedents. *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1741 (2007). The Court did not, however, discard the TSM test completely; it noted that its precedents show that an invention "composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." *Id.*

The Court held that the TSM test must be applied flexibly, and take into account a number of factors "in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed." *Id.* at 1740-41. Despite this flexibility, however, the Court stated that "it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the [prior art] elements in the way the claimed new invention does." *Id.* "To facilitate review, this analysis should be made explicit." *Id.*

The obviousness rationale addressed in *KSR* was premised on combining elements known in the prior art. *Id.* at 1738-39. A parallel analysis applies, however, to a rejection premised on the obviousness of modifying a known composition to change its properties.

The *KSR* Court noted that obviousness cannot be proven merely by showing that the elements of a claimed device were known in the prior art; it must be shown that those of ordinary skill in the art would have had some "apparent reason to combine the known elements in the fashion claimed." *Id.* at 1741.

In the same way, when the prior art teaches away from the claimed solution as presented here (FF12, FF20, FF22 and FF 24), obviousness cannot be proven merely by showing that a known composition could have been modified by routine experimentation or solely on the expectation of success; it must be shown that those of ordinary skill in the art would have had some apparent reason to modify the known composition in a way that would result in the claimed composition.

The Examiner has not persuasively explained why a person of ordinary skill in the art would have had a reason to modify the compositions taught by Evans, Greff '767, or Taki in a way that would result in the compositions defined by the claims on appeal. Therefore, the Examiner has not made out a prima facie case of obviousness under 35 U.S.C. § 103. We reverse the rejections of claims 1-13 and 15-17 as obvious in view of Evans; the rejection of claims 1-17 as obvious in view of Greff '767; and the rejection of claims 1-6, 9, 10, and 14-17 as anticipated by or obvious in view of Taki.

SUMMARY

The rejections on appeal are not supported by a preponderance of the evidence in the record and are therefore reversed.

REVERSED

Ssc:

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